

Notice of Allowability

Application No.

10/540,616

Examiner

Yong Chu

Applicant(s)

LINDERS ET AL.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 04/02/2007.
2. ☒ The allowed claim(s) is/are 13, 23-30 and 32 (renumbered as 1-10).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

DETAILED ACTION

Claims 13, and 23-32 are pending in the instant application and will be examined on the merits.

Response to Amendment

The amendment by Applicants' representative David Knasiak dated on 04/02/2007 has been entered.

Response to Arguments

Argument over rejection of claims 13, 23-24, 26-27, 30 and 32 under 35 U.S.C. §103(a)

The rejection of claims 13, 23-24, 26-27, 30 and 32 under 35 U.S.C. §103(a) is obviated by the amendment of canceling U as hydrogen or C₁₋₄ alkyl. Therefore, the rejection is withdrawn.

Claim objection over claims 13, 23-24, 26-27, 30 and 32

After the rejected claims were overcome by the amendment, examination was extended to cover all the claims. Therefore, the objection to containing non-elected species is withdrawn.

Examiner's amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended with authorization from Applicants representative Mr. David Knasiak dated on 05/23/2007 as follows:

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In claim 13 line 10, delete "hydrogen, C₁₋₄alkyl," after "U represents".

In claim 27 line 2, delete "hydrogen," after "wherein U represents" of line 1.

In claim 29 line 2, delete "preferably" after "... heterocycle selected from".

In claim 30 line 2, delete ", as an active ingredient, an effective 11 β -HSD1 inhibitory amount of" after "pharmaceutically acceptable carrier and".

Delete claim 31.

Delete claim 32, and replace it with new claim 32 as follows:

Claim 32. (Previously presented) A compound according to claim 13, wherein the compound is:

(1 α ,2 β ,3 β ,5 β ,7 β)-N-(5-hydroxytricyclo[3.3.1.1^{3,7}]dec-2-yl)- α , α -dimethyl-benzeneacetamide;
(1 α ,2 β ,3 β ,5 β ,7 β)-N-(5-hydroxytricyclo[3.3.1.1^{3,7}]dec-2-yl)- α , α -dimethyl-3-methyl-benzeneacetamide;
(1 α ,2 β ,3 β ,5 β ,7 β)-N-(5-hydroxytricyclo[3.3.1.1^{3,7}]dec-2-yl)- α , α -dimethyl-3-methoxy-benzeneacetamide;
(1 α ,2 β ,3 β ,5 β ,7 β)-N-(5-hydroxytricyclo[3.3.1.1^{3,7}]dec-2-yl)- α , α -dimethyl-3-hydroxy-benzeneacetamide;
(1 α ,2 β ,3 β ,5 β ,7 β)-N-(5-hydroxytricyclo[3.3.1.1^{3,7}]dec-2-yl)- α , α -dimethyl-3,5-dimethyl-benzeneacetamide);
(1 α ,2 β ,3 β ,5 β ,7 β)-N-(5-hydroxytricyclo[3.3.1.1^{3,7}]dec-2-yl)-3-(phenylmethoxy)benzeneacetamide;
(1 α ,2 β ,3 β ,5 β ,7 β)-N-(5-hydroxytricyclo[3.3.1.1^{3,7}]dec-2-yl)- α , α -dimethyl-3-(carboxymethoxy)-benzeneacetamide;
(1 α ,2 β ,3 β ,5 β ,7 β)-N-(5-hydroxytricyclo[3.3.1.1^{3,7}]dec-2-yl)- α , α -dimethyl-3-[2-(4-morpholinyl)ethoxy]-benzeneacetamide;

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(1 α ,2 β ,3 β ,5 β ,7 β)-N-(5-fluorotricyclo[3.3.1.1^{3,7}]dec-2-yl)- α , α -dimethylbenzeneacetamide;

(1 α ,2 β ,3 β ,5 β ,7 β)-N-(5-methoxytricyclo[3.3.1.1^{3,7}]dec-2-yl)- α , α -dimethylbenzeneacetamide;

(1 α ,2 α ,3 β ,5 β ,7 β)-N-(5-methoxytricyclo[3.3.1.1^{3,7}]dec-2-yl)- α , α -dimethylbenzeneacetamide;

3-(3-{2-[(5-fluoro-2-adamantyl)amino]-1,1-dimethyl-2-oxoethyl}-5-methylphenyl)propanoic acid;

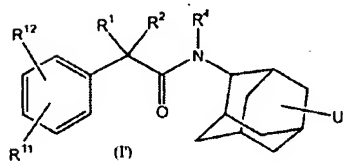
4-(3-{2-[(5-hydroxy-2-adamantyl)amino]-1,1-dimethyl-2-oxoethyl}-5-methylphenyl)butanoic acid;

tert-butyl-4-[3-(3-{2-[(5-hydroxy-2-adamantyl)amino]-1,1-dimethyl-2-oxoethyl}-5-methylphenyl)propanoyl]-1,4-diazepane-1-carboxylate;

or a *N*-oxide, a pharmaceutically acceptable addition salt or a stereochemically isomeric form thereof.

Reasons for Allowance

The present invention is directed to a compound of formula (I')



disclosed in claim 13,

the *N*-oxide forms, the pharmaceutically acceptable addition salts and the stereochemically isomeric forms thereof wherein

R¹ and R² each independently represents hydrogen, C₁₋₄alkyl, NR⁹R¹⁰, C₁₋₄alkyloxy or Het³-O-C₁₋₄alkyl; or

R¹ and R² taken together with the carbon atom with which they are attached from a C₃₋₆cycloalkyl;

R⁴ represents hydrogen, C₁₋₄alkyl, or C₂₋₄alkenyl;

U represents C₁₋₄alkyloxy, phenyl, halo, oxo, carbonyl or hydroxyl;

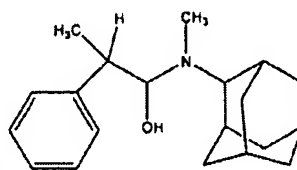
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R^5 and R^6 are each independently selected from hydrogen, C_{1-4} alkyl, C_{1-4} alkyloxy C_{1-4} alkyl, C_{1-4} alkyloxycarbonyl, C_{1-4} alkylcarbonyl, C_{1-4} alkylcarbonyl substituted with one or where possible two or three substituents each independently selected from halo, C_{1-4} alkyl, and C_{1-4} alkyloxy or R^5 and R^6 each independently represent C_{1-4} alkyl substituted with phenyl;

R^7 and R^8 are each independently selected from hydrogen or C_{1-4} alkyl;

R^9 and R^{10} are each independently selected from hydrogen, C_{1-4} alkyl or C_{1-4} alkyloxycarbonyl;

, a pharmaceutical composition comprising the said compounds. The closest prior art of record is by Lavrova *et al.*



Lavrova *et al.* disclose a compound

This compound has

distinct structure from the instantly claim compounds, wherein the **U** is C_{1-4} alkyloxy, phenyl, halo, oxo or hydroxyl for instant application and **U** is H for the closest reference.

Therefore, claims 13, 23-30, and 32 are allowed.

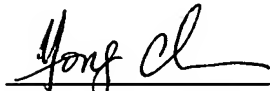
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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